

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 15280-3421PC	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US98/25742	International filing date (day/month/year) 04/12/1998	Priority date (day/month/year) 05/12/1997
International Patent Classification (IPC) or national classification and IPC C12N15/30		
<p>Applicant THE GOVERNMENT OF THE UNITED STATES OF ...et al.</p> <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application 		

Date of submission of the demand 01/07/1999	Date of completion of this report 09.03.00
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I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-47 as originally filed

Claims, No.:

1-50 as originally filed

Drawings, sheets:

1/7-7/7 as originally filed

2. The amendments have resulted in the cancellation of:

the description, pages:
 the claims, Nos.:
 the drawings, sheets:

3. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application.
 claims Nos. 9-14,40-43,50.

because:

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the said international application, or the said claims Nos. 9-14,40-43,50, with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims 2-50
	No:	Claims 1

Inventive step (IS)	Yes:	Claims 2-50
	No:	Claims 1

Industrial applicability (IA)	Yes:	Claims 1-8,15-39,44-49
	No:	Claims

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 9-14, 40-43, 50 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1). The present international application relates to transmission blocking vaccines for malaria by using the Plasmodium (P.) vivax Pvs28-, Pvs25 polypeptides or Pvs25/Pvs28 fusion proteins.

2.1). Reference is made to the following documents:

D1: WO8910936

2.2). D1 which is identical to US7188918 relates to the 25 KD surface protein of zygotes and ookinetes of P. falciparum, said surface protein having been designated Pfs25. The Pfs25 amino acid sequence has 44.8% identity in 221 AA overlap with SEQ ID No 4 of the present application and the encoding sequence (SEQ ID No 1) has 58.7% identity in 661 bp overlap with SEQ ID NO 3 of present application (D1, Fig. 1).

3.1). D1 is novelty destroying for claim 1, since a sequence having about 59% identity hybridizes under stringent conditions to the claimed sequence. Therefore, the characterization of the subject-matter of claim 1 would not allow the skilled person to unambiguously distinguish claim 1 from the disclosures

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made in D1.

Therefore, claim 1 does not meet the requirements of Art. 32 (2) PCT.

3.2). The subject-matter of claims 2-50 was neither disclosed nor suggested in the available prior art, and therefore, it could not be deduced in an obvious manner from the closest prior art document D1.

In consequence, claims 2-50 meet the requirements of Art. 33 (2) and (3) PCT.

4). For the assessment of the present claims 9-14,40-43, and 50 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Claims 1-8,15-39, 44-49 meet the requirements of Art. 33 (4) PCT.

Re Item VIII

Certain observations on the international application

Certain observations on the international application

The characterization of the claimed matter only by its name and without giving a sufficient characterization by true technical features does not allow the skilled person to unambiguously identify the claimed matter.

Therefore, claims 4,6,9,13,15,19,30,40,44 and the claims depending therefrom do not meet the requirements of Art. 6 and Rule 6 PCT.

The above comment also applies to the claims referring back to the above mentioned claims.